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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/540,209 | 04/04/2000 | Gary L. Breton | 2709.1001001 | 9843 |

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| EXAMINER |
|---|
| SAKELARIS, SALLY A |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | 7 |

DATE MAILED: 05/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/540,209 | Applicant(s) BRETON, GARY L. | |
|---|---|---|---|
| | Examiner Sally A Sakelaris | Art Unit 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *04 April 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

***RESTRICTION***

1. Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-13 are drawn to 5222 different polynucleotide sequences, vectors, host cells, methods for expression of nucleic acids and as a vaccine composition, classified in Class 435, subclasses 69.1, 252.3, and 320.1, Class 536, subclass 23.5, 24.31 and 24.33. Class 514, subclass 44.

II. Claims 14-16 are drawn to a method of treating by using 5222 different nucleic acid composition as classified in Class 514, subclass 44.

III. Claims 17-20 are drawn to 5222 different polypeptides and vaccine composition, classified in Class 530, subclass 350 and Class 424 subclass 1.69.

IV. Claims 21-23 are drawn to a method of treating by using 5222 different polypeptide compositions as classified in Class 514, subclass 2.

V. Claim 24 is drawn to a method of detecting 5222 different nucleic acids, classified in Class 435, subclass 6.

VI. Claims 25 and 26 are drawn to a computer readable format for 5222 different nucleotide sequences as classified in Class 702, subclass 19.

VII. Claims 27 and 28 are drawn to a method of identifying 5222 different nucleic acids through bioinformatics as classified in Class 435, subclass 6 and Class 702, subclass 19.

2. The inventions are distinct, each from the other because of the following reasons:

a. Inventions I and III are patentably distinct in structure and physiochemical properties. Invention I is drawn to nucleic acids whereas invention III is drawn to proteins. Because nucleic

acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the proteins may be utilized in ligand binding assays or to generate antibodies. The protein of invention III does not require the particular products of the nucleic acids of group I since the proteins of invention III can be isolated from natural sources or chemically synthesized.

b. Inventions I and VI are patentably distinct in structure and physiochemical properties. Invention I is drawn to nucleic acids whereas invention VI is drawn to a computer readable format. Because nucleic acids are composed of nucleotides while the computer readable format is comprised of the computer hardware and software necessary for the manipulation of sequence data digitally. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the product of Group VI can be used in a storage capacity or as a searchable databank for the inclusion of text of any subject matter, from the books in a library's collection to an inventory of a retail store. The computer readable format of invention VI does not require the particular products of the nucleic acids of group I. Therefore, the inventions of groups I and VI are patentably distinct from each other.

c. Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the nucleic acids of invention I are not required to practice the methods of invention IV involving polypeptides.

d. Groups I and II and I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used in a materially different process such as for sequencing reagents and involving amplification and sequencing methods in order to achieve the objective of genotyping an individual for pedigree analysis or can be used for protein synthesis.

e. Groups I and VII are related as product and method of using product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I can be used in a materially different process aside from the method of Group VII. For example, the nucleic acids can be used for synthesizing proteins or for therapeutics.

f. Group III and Group VI are patentably distinct in structure and physiochemical properties. Invention III is drawn to polypeptides whereas invention VI is drawn to a computer readable format. Because polypeptides are composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain) while the computer readable format is comprised of the computer hardware and software necessary for the manipulation of sequence data digitally. The computer readable format of invention VI does not require the

particular products of the polypeptides of group III. Therefore, the inventions of groups III and VI are patentably distinct from each other.

g. Groups III and II, III and V, and III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the polypeptides of invention III are not required to practice the methods of inventions II, V, and VII involving polynucleotides and computer readable formats.

h. Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be used in materially different process aside from the method of Group IV. For example, the polypeptide may be used to raise antibodies and to purify the antibodies.

i. The inventions of Groups II, IV, V and VII are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. Group II is drawn to a method of treatment using a polynucleotide composition. Group IV is drawn to a method of treatment using a polypeptide composition. Group V is drawn to a method of detecting nucleic acids. While finally, Group VII is drawn to a method of diagnosis by determining the presence or amount of expression of the polypeptide. The methods all have

different method steps, objectives and reagents. Therefore the methods are distinct over one another.

**Sequence Election Requirement Applicable to All Groups:**

3. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to a nucleotide sequence, the Applicants must elect a single nucleic acid sequence from SEQ ID NOS: 1-5222 and a single nucleic acid sequence encoding a polypeptide from SEQ ID NOS: 5223-10444.(See MPEP 803.04).

**Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.**

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter and because these inventions require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

5/02/02

CARLA J. MYERS
PRIMARY EXAMINER